DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Arthrex Inc.
Mr. David L. Rogers
Regulatory Affairs Associate
1370 Creekside Boulevard
Naples, Florida 34108-1945

April 29, 2015

Re: K150456
Trade/Device Name: Arthrex Plates, Screws, and Staples
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC, JDR
Dated: April 7, 2015
Received: April 8, 2015

Dear Mr. David L. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150456

Device Name
Arthrex Plates, Screws, and Staples

Indications for Use *(Describe)*
The Arthrex Modified Osteotomy System, designed for Opening Wedge Distal Tibial, Distal Femoral, Proximal Tibial osteotomies, and High Tibial Closing Osteotomies, is used in conjunction with bone screws to provide fixation following surgery. Specifically for use in treatment of non-union, malunion, and fractures of proximal tibia, distal femur, and distal tibia including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures. Specially sloped plates can be used in cases when a tibial slope adjustment is needed. This system consists of plates and screws which join together to correct abnormalities or trauma related injuries. It is intended to be used with adequate post-operative immobilization.

The Arthrex Humeral Fracture Plates and Screws are intended to provide internal fixation of proximal fractures of the humerus.

The Arthrex Compression Staple is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodesis or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition, and stabilize metatarsus primus varus.

The Arthrex Distal Extremity Plate System is intended for use in stabilization of fresh fractures, revision procedures, osteotomies, joint fusion and reconstruction of small bones and bone fragments of the hand/wrist, foot/ankle, and osteopenic bone.

The Arthrex Compression Plates are intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle, foot, hand and wrist, such as opening wedge osteotomies of Hallux Valgus.

The Arthrex Distal Radius Plate System is intended for internal fixation for fractures and reconstruction of the small bones, primarily including the distal radius and distal ulna. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and malunions. This system can be used for palmar, dorsal or orthogonal application.

The Arthrex Compression FT Screw is intended for fixation of small bone fragments, such as apical fragments, osteochondral fragments and cancellous fragments. Specific applications include the following: Osteochondral fragments (talar vault, femoral condyle); Apical fragments (radial head, patellar rim, navicular, metacarpal/metatarsal); Cancellous fragments (talus); Carpal, metacarpal, and small hand bone; Tarsal and metatarsals; Phalanges; Intra-articular fractures; Ankle; Proximal and distal humerus; Proximal and distal radius; Proximal and distal ulna; Osteochondral fixation and fractures; Osteochondritis Dissecans; Fixation of fractures and osteotomies about the knee; Oblique fractures of the fibula; Reconstructive surgeries of the foot; Malleolar fixation

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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2.6 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared	April 9, 2015
Manufacturer/Distributor/Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	David L Rogers Regulatory Affairs Associate Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 71924 Fax: 239/598.5508 Email: david.rogers@Arthrex.com
Trade Name	**Arthrex Plates, Screws, and Staples**
Common Name	Plate, fixation, bone, staple
Product Code -Classification Name ***CFR***	HRS – Plate, Fixation, Bone HWC – Screw, Fixation, Bone JDR – Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Predicate Device	*K014155: Arthrex Modified Osteotomy System* *K041965: Arthrex Humeral Fracture Plates & Screws* *K080111: Arthrex Compression Staple* *K111253: Arthrex Distal Extremity Plate System* *K130510: Arthrex Compression Plates* *K131474: Arthrex Distal Radius Plate System* *K132217: Arthrex Compression FT Screws*
Purpose of Submission	This **special 510(k)** premarket notification is intended to address the use of Gamma Irradiation and Ethylene Oxide sterilization on the ***Arthrex Plates, Screws, and Staples*** devices, which were originally cleared as non-sterile devices under K014155, K041965, K080111, K111253, K130510, K131474, K132217. The intended use, material, and fundamental technological characteristics of the proposed ***Arthrex Plates, Screws, and Staples*** are substantially equivalent to the non-sterile predicates.
Device Description	The ***Arthrex Plates, Screws, and Staples*** is a family of

	plates, screws, and staples manufactured from stainless steel or titanium that will be offered as sterile or non-sterile devices in various sizes for use in orthopedic surgery.
Intended Use	*The **Arthrex Modified Osteotomy System**, designed for Opening Wedge Distal Tibial, Distal Femoral, Proximal Tibial osteotomies, and High Tibial Closing Osteotomies, is used in conjunction with bone screws to provide fixation following surgery. Specifically for use in treatment of non-union, malunion, and fractures of proximal tibia, distal femur, and distal tibia including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures. Specially sloped plates can be used in cases when a tibial slope adjustment is needed. This system consists of plates and screws which join together to correct abnormalities or trauma related injuries. It is intended to be used with adequate post-operative immobilization.* *The **Arthrex Humeral Fracture Plates and Screws** are intended to provide internal fixation of proximal fractures of the humerus.* *The **Arthrex Compression Staple** is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodesis or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition, and stabilize metatarsus primus varus.* *The **Arthrex Distal Extremity Plate System** is intended for use in stabilization of fresh fractures, revision procedures, osteotomies, joint fusion and reconstruction of small bones and bone fragments of the hand/wrist, foot/ankle, and osteopenic bone.* *The **Arthrex Compression Plates** are intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle, foot, hand and wrist, such as opening wedge osteotomies of Hallux Valgus.*

	*The **Arthrex Distal Radius Plate System** is intended for internal fixation for fractures and reconstruction of the small bones, primarily including the distal radius and distal ulna. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and malunions. The system can be used for palmar, dorsal or orthogonal application.* *The **Arthrex Compression FT Screw** is intended for fixation of small bone fragments, such as apical fragments, osteochondral fragments and cancellous fragments. Specific applications include the following:* • *Osteochondral fragments (talar vault, femoral condyle)* • *Apical fragments (radial head, patellar rim, navicular, metacarpal/metatarsal)* • *Cancellous fragments (talus)* • *Carpal, metacarpal, and small hand bone* • *Tarsal and metatarsals* • *Phalanges* • *Intra-articular fractures* • *Ankle* • *Proximal and distal humerus* • *Proximal and distal radius* • *Proximal and distal ulna* • *Osteochondral fixation and fractures* • *Osteochondritis Dissecans* • *Fixation of fractures and osteotomies about the knee* • *Oblique fractures of the fibula* • *Reconstructive surgeries of the foot* • *Malleolar fixation*
Substantial Equivalence Summary	The ***Arthrex Plates, Screws, and Staples*** is substantially equivalent to the predicate devices in which the basic design features and intended uses are the same. Any differences between the ***Arthrex Plates, Screws, and Staples*** and the predicates are considered minor and do not raise questions concerning safety and effectiveness. All devices subject to this submission were previously cleared as non-sterile devices. The proposed devices will undergo Gamma Irradiation or Ethylene Oxide

	(EO) sterilization. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex, Inc. has determined that the ***Arthrex Plates, Screws, and Staples*** is substantially equivalent to the predicates.